

NIH Training Workshop: *Patient Recruitment Strategies*

December 10, 2003

Strategic Health Communications

Clinical Trial Facts

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

Did you know:

- Only 4% of U.S. population participates in clinical trials
- \$1.76 billion of \$8 billion total annual clinical research spending is dedicated to patient enrollment efforts
- 85% of trials don't finish on time, due to low patient accrual
- 30% of trial sites fail to enroll even a single patient
- Only 1 out of 20 patients who respond to clinical trial recruitment promotions enrolls in a study
- 65-80% of clinical trials conducted in the U.S. don't meet their temporal end points, largely due to challenges in patient recruitment

HOW DO WE CHANGE THESE FACTS?

Patient Recruitment should be:

- Client Focused: Understand the Study Goals
- Research Based: Understand the Audiences
- Results Oriented: Strategies designed to meet primary and secondary goals

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

Establish Uniform and Consistent Process

MMG Process Model

Back to:

[Facts](#)

[MMG
Process
Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

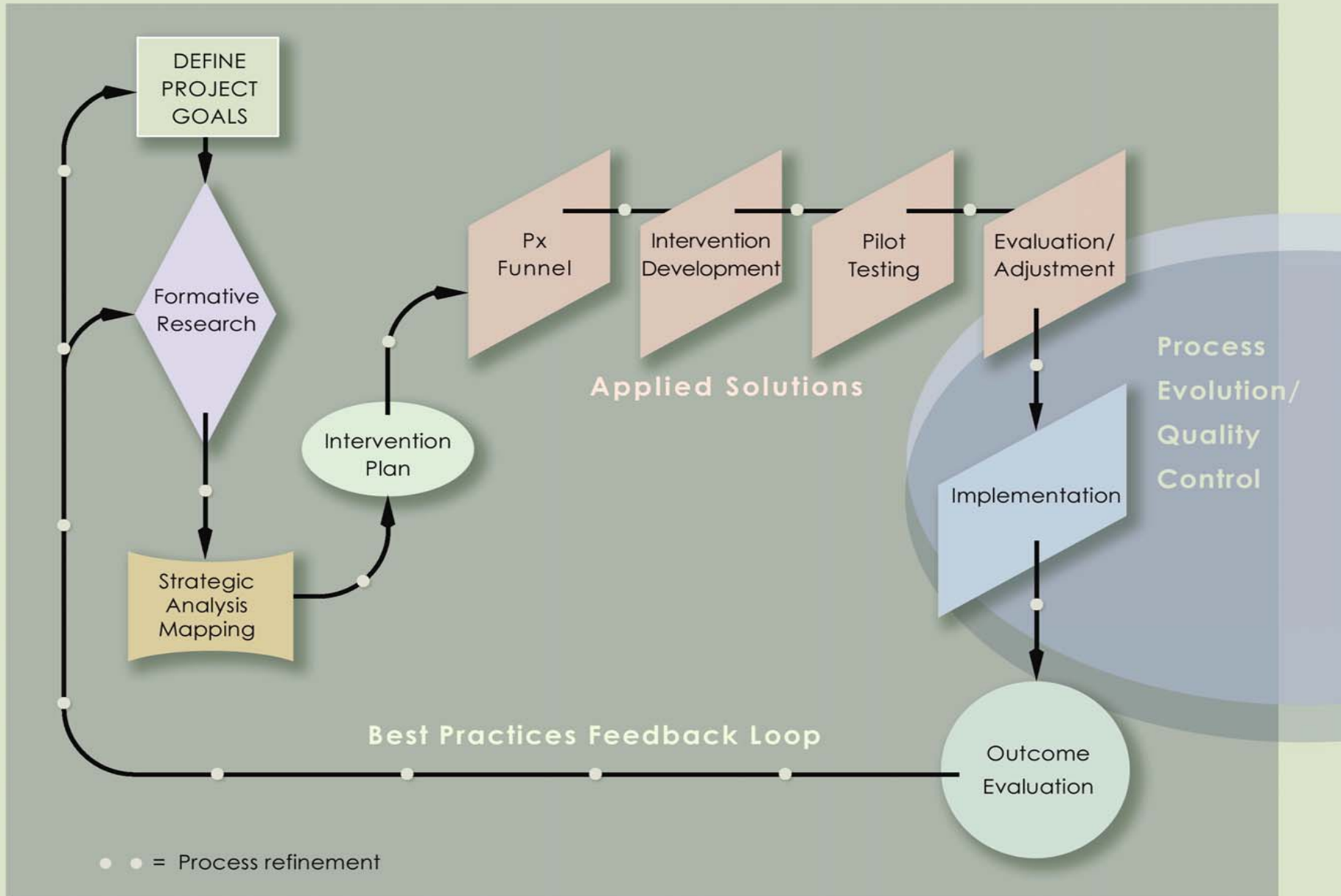
[Strategy](#)

[MMG
Capabilities](#)

[Summary](#)

- Define Project Goals and Challenges:
 - Clearly define primary study goals and possible secondary organizational goals
 - Think strategically as protocol is developed and throughout recruitment process
- Conduct Research
 - Secondary
 - Formative
- Create Strategic Analysis Maps
- Develop Intervention Plan
- Evaluate

MMG Strategic Process Model



Identify the Challenges.....

Know the Environment

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

- Understand the disease and dynamics behind the health behaviors of the population
- Health communications is about:
 - Understanding your audiences (research)
 - Building an identity (branding)
 - Providing information audiences will understand and trust (message development and delivery)

Identify the Challenges...Know the Barriers to Recruitment & Retention

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

Technical Factors:

- Competing trials
- Standards of care
- Poor site selection
- Protocol parameters
- Off-label use of protocol drugs
- Complicated, confusing consent forms

Personal Factors:

- Bad press/horror stories
- Cultural attitudes
- Transportation
- Placebo/randomization
- “Guinea pig” syndrome
- Beliefs that clinical trials are only for the terminally ill

Identify the Challenges.....

Know your Participant Population

Back to:

[Facts](#)

[MMG](#)
[Process](#)
[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)
[Capabilities](#)

[Summary](#)

- Trust (whom people trust, whom they don't)
- Special populations (women, minorities, elderly, rural, and poor) often require targeted intervention plans with grassroots outreach activities

One study shows:

- 1/3 of African American women avoided clinical trials because they didn't trust scientists
- 37% expressed a preference to be treated by an African American doctor
- Only 28% felt clinical research in the U.S. is ethical



Research and evaluation

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

- Audience research
 - Demographic
 - Geographic
 - Behavioral
 - Psychographic
 - Incidence and prevalence
- Formative research

Research

Audience Research:

- Obtain demographic information about the audience(s)
 - Who they are
 - What their age is
 - Where they live
 - What is the ethnic/cultural predominance
- What can the data tell you?
 - Whom they will go to for information (trusted sources)
 - Where sites should be located
 - Types of PIs needed (minority)

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

Research *continued*

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

Formative Research:

- Identifies individuals in target audiences: (participants, family, health care professionals, PIs)
- Determines disease-specific knowledge level:
 - What they know about the disease
 - What motivates them to join a CT
 - How do they get information
 - Perceived obstacles

Data Allow:

- Strategies tailored to deliver a targeted message, to the exact audience
- Development of recruitment, retention, and adherence strategies

Case Study 1: Formative Concept Testing

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

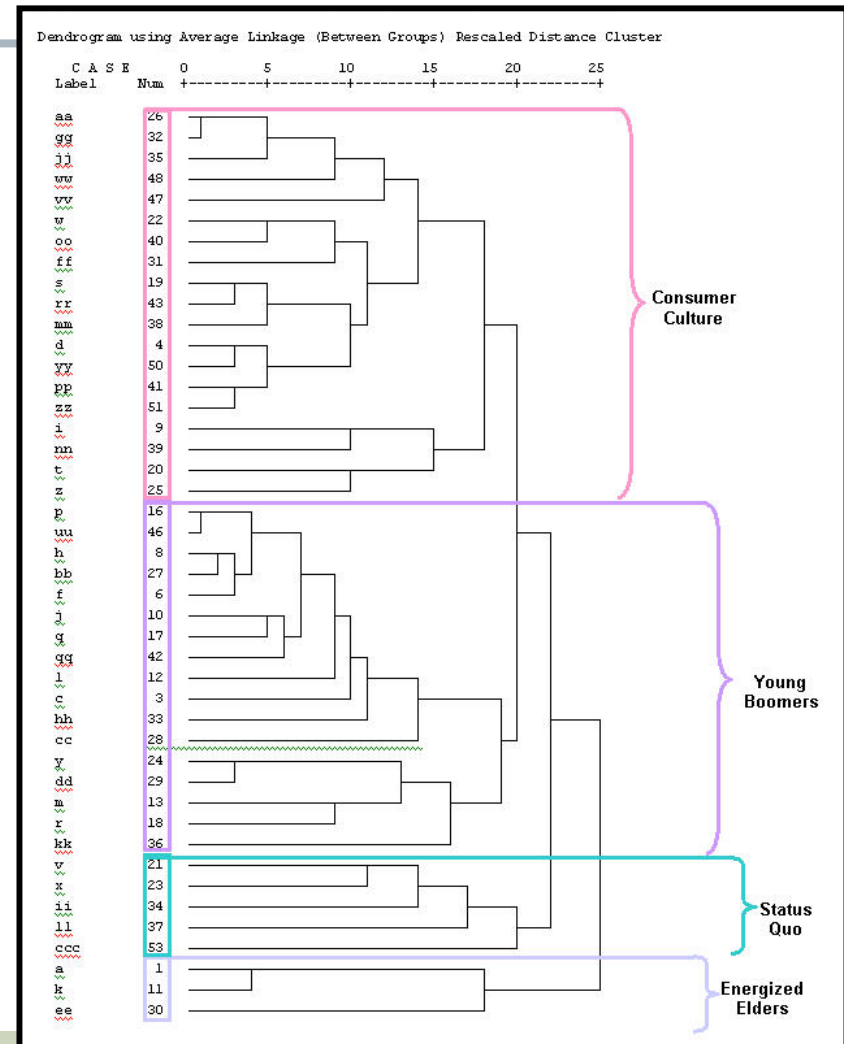
[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

- Testing of materials
- Explored attitudes, knowledge & beliefs
- Uncovered health beliefs/trust issues related to clinical trial participation
- Determined psychographics



Case Study 1: Results

Back to:

[Facts](#)

[MMG](#)
[Process](#)
[Model](#)

[Challenges](#)

[Research](#)

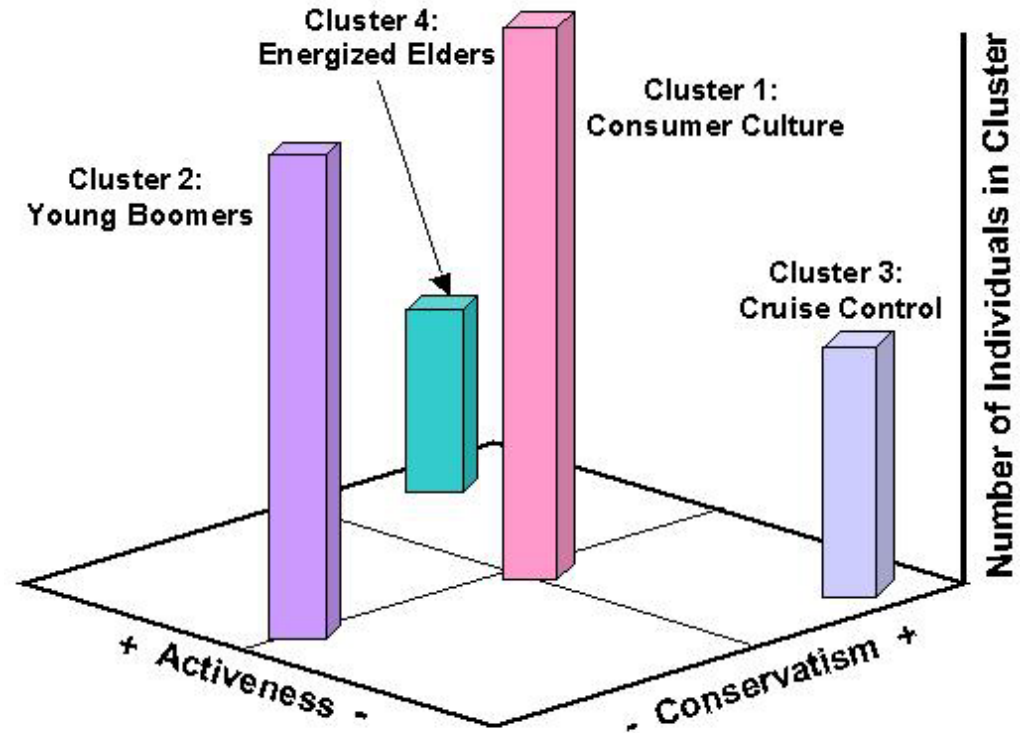
[Case Studies](#)

[Strategy](#)

[MMG](#)
[Capabilities](#)

[Summary](#)

- Informed tailored strategies
- Informed marketing plan
- Demonstrated value of multiple approaches



Case Study 2: Messages that Resonate with Patients

Back to:

[Facts](#)

[MMG
Process
Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG
Capabilities](#)

[Summary](#)

- Focused In-depth Interviews
- Reactions to Messages / Images
- Targeted Ad Placement



My mommy's still sad

Is this how your family sees you?

Do you suffer from major depression? Have standard treatments failed to restore your old self?

About 1 in 20 people suffers from major depression. And one-third of that group doesn't show adequate response to standard treatments. Right now, a new treatment is being studied that may offer the relief you've been searching for. To participate in a free trial of an investigational drug for depression, call this toll-free number.

1-888-555-4488

Case Study 2: Results

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

- Identified messages
- Identified strategic placement
- Filled trial 3 months early



Strategic Analysis Mapping (SAM)



ALLIANCE FOR DRUG DEVELOPMENT

GOALS

- Develop a new drug that both shortens duration of and/or simplifies treatment, is effective against MDR TB, addresses both active latent forms of disease, and is affordable for equitable access
- Establish the Alliance as the catalyst for drug development

Identify & Access Promising Compounds

OBJECTIVES:

- Evaluate drug candidates
- Enroll a minimum of 16 lead compounds in portfolio by the end of 2006
- Ensure affordability through strategic agreements

AUDIENCES:

- Pharma/ Biotech
- Academia/ Public Research Labs
- Compound Libraries
- Compound screening programs

STRATEGIES:

- Map/identify existing compounds and their viability for drug development
- Permanent scouting in industry (R&D)

Oversee the Development of Compounds

OBJECTIVES:

- Manage outsourcing of portfolio compounds development
- Monitor and interview to advance external partnerships (non portfolio compounds)

AUDIENCES:

- CROs
- Industry
- Research Institutions

STRATEGIES:

- Identify a roster of qualified providers worldwide
- Enlist consortium members as possible in-kind partners
- Establish an R&D plan for each portfolio

Clinical Trials Planning & Execution

OBJECTIVES:

- Conduct trials according to FDA-EMEA requirements and highest ethical standards
- Streamline clinical trials

AUDIENCES

- Potential Sites/PIs
- CDC, NIH and other MRCs
- Governments, Patient Advocates

STRATEGIES:

- Identify and secure commitment of countries/viable sites and partner institutions (R&D, A)
- Ensure timely start of clinicals based on portfolio progress (R&D)

Regulatory Approval & Requisition

OBJECTIVES:

- Fast-track approval and harmonization of drug development

AUDIENCES

- Regulatory agencies (EMA, FDA, etc.)
- Governments

STRATEGIES:

- Assess strategies to streamline clinical trials and registration (R&D)
- Support development of surrogate markers (R&D)
- Determine if FDA standard is essential to portfolio drugs (R&D, A)

Mobilize Resources for Drug Development

OBJECTIVES:

- Raise \$400 million over 10 years including \$150 million in in-kind services
- Ensure continued momentum through public awareness
- Attract the necessary expertise and experience to the Alliance

AUDIENCES

- Governments
- Foundations
- Corporate Philanthropy
- Pharma/ Biotech

STRATEGIES:

- Advocate for investments in basic and translational research (A, R&D)





Pediatric anxiety study

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

- Goal: 350 randomized
- What worked:
 - Radio advertising
 - Direct scheduling
 - Assist struggling sites immediately
 - Monitor site performance
- Outcomes:
 - 567 randomized
 - Completed 8 weeks ahead of schedule

Adult Depression Study

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

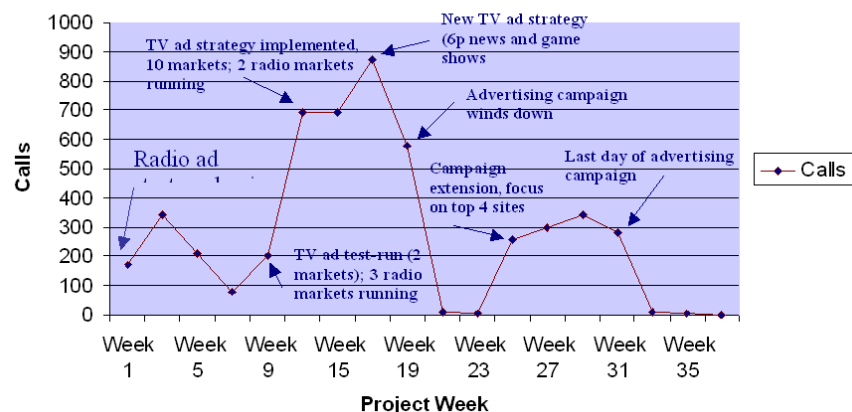
[MMG](#)

[Capabilities](#)

[Summary](#)

- **Goal:** To help recruit 140 adults for two adult multi-center double blind, placebo-controlled depression trials over a 9-month period.
- **What worked:** television advertising, supplemented by radio, print, and Internet advertising.
- **Outcomes:**
 - Screened 6,876 callers
 - Referred 1,673 to sites
 - Achieved 147 randomizations
 - Developed model approaches for working on mental health trials

Adult Depression Study Performance



Pediatric Depression Study

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

- **Goal:** 265 children ages 6 to 17 over a 15-month period, with a requirement of equal numbers 6-11 and 12-17
- **What worked:** advertising, local and national outreach, media relations, and Internet
- **Results:**
 - Completed recruitment on time with 285 total randomizations.
 - Received over 4,600 calls to the phone center and nearly 1,550 referrals were sent to the sites
 - Responded to seasonal and age distribution fluctuations by developing three television ads
 - Daily monitoring of advertising resulted in the most cost-effective media buys

Summary

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

- Start early-when protocol is being developed
- Know your audience:
 - who they are
 - how they receive information
 - where they are
- Develop strategy based on research
- Select sites that can deliver target audience
- Develop all materials with target audience in mind
- Evaluate and modify
- Spend early, spend wisely and spend as little as possible

MMG Capabilities

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

Specializations:

Integrated function-based staff

Strategic relationships and partnerships

Strategic research-based business model

Clinical Trial Support:

Branding

Enrollment

Retention & Adherence

Site Assistance

Pre-launch Planning

In-House Service Offerings:

Media planning and monitoring

Media relations

Ambassador ProgramSM

Creative services

New media

Call center

Health and science writing

Meeting and event planning

Research

Sources

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

Harris Interactive. There are many reasons why people are reluctant to participate in clinical trials. *Health Care News*. Vol. 2, Issue 7, March 26, 2002

www.harrisinteractive.com/news/newsletters/healthnews/
[HI_HealthCareNews2002Vol2_Iss07.pdf](#)

Accessed January 29, 2003.

Study Subjects Want..

- Simple explanation of the study
- Clear understanding of what is expected of them
- Clear understanding of what the potential benefits and risks are
- Who to contact if they have questions or concerns
- To know they can quit at any time
- To know the results
- To feel appreciated and valued

Customer Service

- Explain the study in simple terms
- Make yourself available for their follow-up questions
- Offer reimbursement for travel, parking, meals
- Write a thank you note
- Send them a birthday card
- Provide them with study results

Patient Tools

- Study brochure
- Q&A
- FAQ
- Key contacts
- Patients rights
- List of additional resources
- Thank you cards, birthday cards
- Gift certificates, coupons

Build the Referral Network

- Make a list of health care providers (HCPs) coming in contact with potential enrollees
- Recruit them to a lunch and learn session
- Ask for help
- Keep them informed
 - Study start date and close date
 - Enrollment status
 - Type of patient
- Thank them for helping

Referral Network Tools

- Study brochure
- Study reference card
- Poster
- Flyers
- Dear Colleague letter/emails
- Employee newsletter article
- PowerPoint presentation
- Reminder items
- Thank you items
 - Food
 - Gift certificates

Stroke study

Back to:

[Facts](#)

[MMG](#)

[Process](#)

[Model](#)

[Challenges](#)

[Research](#)

[Case Studies](#)

[Strategy](#)

[MMG](#)

[Capabilities](#)

[Summary](#)

- **Goal:** Recruit 1,300 individuals for international acute ischemic stroke study (ongoing)
- **What's working:** public awareness campaign, branding, reminder items, outreach to emergency departments
- **Outcomes:** Recruitment is on track with projections



Closed Head Injury (pilot test)

- **Goal:** Help recruit 270 individuals to a 12-week trial conducted at 27 sites across US
- **What worked:**
 - Ambassador program
 - Advertising
 - Media relations
 - Web promotion
- **Outcome:** Large increase in inquiries, referrals, screenings, and randomizations

Thank you!

- For more information, e-mail address is:
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